

**REMARKS**

Favorable consideration and allowance are respectfully requested for claims 1-10 and 12-15 in view of the foregoing amendments and the following remarks.

Claims 1-15 were rejected under 35 U.S.C. 112, second paragraph as indefinite.

In particular, the Examiner queried what is encompassed by "sorting". In response, claim 1 has been amended to clarify that the large-capturing particles are sorted from each other and to clarify a grammatical error (changing the plural "are" to the singular "is").

The Examiner also indicated that claim 1 was confusing because the preamble recited a process for isolating while the last step in the claim was directed to sorting particles. In response, claim 1 has been amended to recite the additional step of detaching the molecules, cells or other sample particles of interest from the large-capturing particles after they are sorted. Accordingly, at the end of the method, one arrives at a set of isolated molecules, cells or other particles and practicing the steps of the method allows one to achieve the stated goal of isolating these molecules, cells or other particles.

Claim 8 was rejected for lacking proper antecedent basis in the phrase "the distinction". In response, claim 8 has been amended to recite the phrase "a

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distinction". This addresses the previous antecedent basis concern cited by the Examiner.

The rejection of claims under 35 U.S.C. 112 is believed to be addressed by the foregoing amendments and remarks and reconsideration and withdrawal thereof are respectfully requested.

Claims 1-10 and 12-15 were rejected under 35 U.S.C. 102(b) as anticipated by Burger et al., U.S. Patent No. 4,904,581. This rejection is respectfully traversed.

As amended, claim 1 includes the limitations of previously-pending claim 11. Claim 11 was previously indicated to be allowable over the Burger reference. See the Office Action at page 11. Accordingly, claim 1 and claims 2-10 and 12-15, which depend from claim 1, are now believed to be allowable over Burger.

Reconsideration and withdrawal of the rejection of claims 1-15 are respectfully requested in view of these amendments and the foregoing remarks.

Claims 1-8 and 10-15 were rejected under 35 U.S.C. 102(b) as anticipated by Sutton et al., U.S. Patent No. 5,308,749. This rejection is respectfully traversed.

As amended, claim 1 recites that the large-capturing articles are larger than 200  $\mu\text{m}$ . The Sutton reference, on the other hand, is directed to the use of particles having a significantly smaller size. In column 8, lines 5-9, the Sutton

reference describes that the average particle size is generally from about 0.01 to about 20  $\mu\text{m}$ . This is an order of magnitude in difference from the size recited in claim 1.

Claim 1, as amended, clearly recites the steps of sorting the large particles having bound molecules, cells or other particles and then detaching the bound molecules, cells or other sample particles from the large particles which initially captured them. The Sutton reference, on the other hand, relates to a method of separating molecules bound to particles and molecules not bound to particles. See, for instance column 15, lines 7-10. The present invention, in contrast, relates to separation of bound particles and unbound particles.

In this regard, the Sutton reference is generally directed toward the use of spectrophotometric measurements to evaluate the type of molecule bound and also to quantify the quantity of molecules bound to all particles at a global level. See column 4, lines 7-9 of the Sutton reference. This is significantly different from the presently claimed invention which provides for separating the large particles which are bound to cells, molecules or other particles from those large particles which are not bound.

Sutton also describes the use of affinity chromatography to separate analytes of interest. See Sutton at column 16, lines 32-40. During affinity chromatography, typically, excess impure solution is washed away from the column with analyte already bound to the column. A separate wash may then be

used to remove the bound analyte of interest from the column. Thus, the analyte of interest is separated from a mixture of both bound and unbound large particles. This is significantly different from the presently claimed method where the large-capturing particles which are bound to molecules, cells or other particles of interest are separated from the unbound large-capturing particles.

Although the Examiner appears to have rejected claim 11 as anticipated by Sutton, there was no explanation or other discussion provided for how Sutton anticipates the invention described by this claim, unlike all of the other rejected claims. As presently amended, claim 1 incorporates the limitations of the previously pending claim 11. Thus, claim 1 makes clear that the presently claimed invention is directed to a method where the large-capturing particles which are bound with the analyte of interest are separated from those large-capturing particles which are unbound, and then the analyte of interest is detached from the large-capturing particles. The Sutton reference does not teach or suggest such a method.

Because the Sutton reference does not teach each and every step of the claimed process, the reference does not anticipate the claim. Accordingly, reconsideration and withdrawal of the rejection of claim 1 and the claims dependant therefrom are respectfully requested.

Claims 1-8 and 10-15 were rejected under 35 U.S.C. 102(b) as anticipated by Wood, U.S. Patent No. 5,290,707. This rejection is respectfully traversed.

As amended, claim 1 relates to a process that uses large-capturing particles which are larger than 200  $\mu\text{m}$  in size. The Wood reference, on the other hand, relates to significantly smaller particles, and provides no teaching or suggestion to use a particle as large as that instantly claimed. For instance, see column 5, lines 1-18, which teaches the use of microspheres varying in size from 1.5 to 4  $\mu\text{m}$ . Like the Sutton reference, the microspheres of the Wood reference are an order of magnitude smaller than the large capturing particles described in presently-pending claim 1.

Moreover, as amended, claim 1 clearly indicates that the large capturing particles bound with molecules, cells or other particles are first separated from the unbound large-capturing particles and then the molecules, cells or other particles of interest are detached from the large-capturing particles. In the Wood reference, on the other hand, the separation is between particles which have bound antigen and those which have bound agglutinating particles. Wood does not teach any isolation of the antigens from the particles. As with the rejection over the Sutton reference, the Office Action provides no discussion or indication of why claim 11 is believed by the Examiner to be anticipated by the Wood reference, unlike the rest of the rejected claims. The limitations of claim 11, as mentioned above, are incorporated into claim 1 by the amendments provided herein.

Further, Applicants submit that the Wood reference provides no teaching of a method such as that set forth in claim 1. The Office Action points to column 5, lines 50-56 of the Wood reference to teach the sorting step of claim 1. However, claim 1, as presently amended, recites a sorting step related to sorting bound large-capturing particles from unbound large-capturing particles. Then, the molecules, cells or other sample particles of interest are separated from the large-capturing particles. In lines 50-56, column 5, the Wood reference provides for sorting based on size. However, this does not amount to separating bound large-capturing particles from unbound large-capturing particles and even further, these methods from the Wood reference do not amount to isolating because there is no teaching of a step for detaching the molecules, cells or other sample particles of interest from the large-capturing particles.

Accordingly, the Wood reference does not teach each and every step of the presently claimed process. Reconsideration and withdrawal thereof are respectfully requested.

Claim 9 was rejected under 35 U.S.C. 103(a) as unpatentable over the Sutton reference in view of McCafferty et al., U.S. Patent No. 5,969,108 as well as over the Wood reference in view of the McCafferty reference. These rejections are respectfully traversed.

The McCafferty reference is cited for teaching that the large-capturing particles bound to molecules, cells or other particles of interest are sorted into

Petri dishes or microtiter plates. Even assuming, *arguendo*, that the McCafferty reference does provide such a teaching to sort the bound large-capturing particles into Petri dishes or microtiter plates, there are significant differences between each of the Sutton and Wood references as described above. In particular, it is clear that neither of these references teaches the use of large-capturing particles of a size as is presently claimed, nor do the references teach a method that involves sorting bound, large-capturing particles from unbound large-capturing particles and subsequently detaching the molecules, cells or other particles of interest from the large-capturing particles to which they are bound.

Accordingly, these references, even when combined, do not teach each and every step of the presently claimed process. Moreover, there is no suggestion or motivation provided to one of skill in the art to try to combine the references. Absent such a suggestion or motivation to combine or otherwise modify a reference, an obviousness rejection based on a combination of references cannot be properly maintained. Reconsideration and withdrawal of these rejections are therefore respectfully requested.

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**Conclusion**

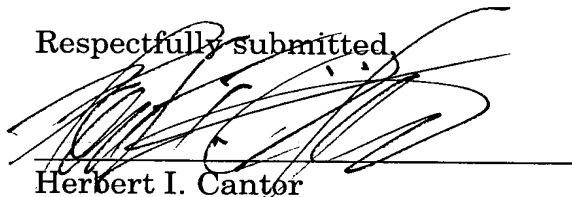
In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Although a Petition for Extension of Time is submitted herewith, if necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 010770.49121US).

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Respectfully submitted,



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